UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,810	02/14/2001	Mary E. Gerritsen	09800081-0023	4070

28443 7590 02/03/2003

BRINKS HOFER GILSON & LIONE

P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER
PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/784,810	Gerritsen et al.
Examiner	**Art Unit**
Scott D. Priebe, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-53 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I & II. Claims 1-4, 38 and 41, drawn to the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 435, subclass 194.

III & IV. Claims 5-14, 39 and 42, drawn to nucleic acids encoding the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 536, subclass 23.5.

V & VI. Claims 15-17, 40 and 43, drawn to antibodies which bind to the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 530, subclass 387.9.

VII & VIII. Claims 18, 44 and 45, drawn to binding assays for detecting or quantifying the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 435, subclass 7.4.

IX & X. Claims 19-21, 46 and 47, drawn to binding assays for detecting or quantifying nucleic acids encoding the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 435, subclass 6.

XI & XII. Claims 22 and 23, drawn to binding assays for identifying ligands of the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 435, subclass 7.1.

XIII & XIV. Claim 24, drawn to cell-based assays for identifying compounds which modulate expression of the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 435, subclass 29.

XV & XVI. Claim 25, drawn to a methods for modulating activity of the polypeptides of SEQ ID NO: 2 and 6, respectively, in a cell with a ligand, classified in class 435, subclass 375.

XVII & XVIII. Claims 26-29 and 48, drawn to methods for treating diseases with the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 514, subclass 2.

XIX & XX. Claims 30-33 and 49, drawn to methods for treating diseases with nucleic acids encoding the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 514, subclass 44.

XXI & XXII. Claims 34-37 and 50, drawn to methods for treating diseases with antibodies which bind to the polypeptides of SEQ ID NO: 2 and 6, respectively,, classified in class 424, subclass 139.1.

XXIII & XXIV. Claim 51, drawn to transgenic animals comprising nucleic acids encoding the polypeptides of SEQ ID NO: 2 and 6, respectively, classified in class 800, subclass 13.

XV & XVI. Claim 52, drawn to assay for compounds which modulate expression or activity of the polypeptides of SEQ ID NO: 2 and 6, respectively, in a transgenic animal, classified in class 800, subclass 3.

XVII. Claim 53, drawn to a transgenic animal with a disruption in a sphingosine kinase gene, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I, III, V, VII, IX, XI, XIII, XV, XVII, XIX, XXI, XXIII and XXV are unrelated to inventions II, IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX, XII, XIV, and XXVI because the polypeptides of SEQ ID NOs: 2 and 6 are structurally different proteins which are not disclosed as being capable of use together, and have different functions and effects. The polypeptides of inventions I and II, the nucleic acids of inventions III and IV, and the antibodies of inventions IV and V are unrelated to each other as they are structurally and functionally different compounds with different modes of operation, functions and effects. The polypeptides of inventions I and II are unrelated to the methods of VII-X, XIII-XVI, XIX-XXII and XXV-XXIV because the polypeptides are not used in these methods. The nucleic acids of inventions III and IV are unrelated to the methods of XI, XII, XV-XVIII, XXI, XXII, XXV, and XXIV because the nucleic acids are not used in these methods. The antibodies of inventions V and VI are unrelated to the methods of IX, X, XIII, XIV, XVII-XX, XXV, and XXVI because the

antibodies are not used in these methods. The transgenic animals of inventions XXIII and XXIV are unrelated to the methods of VII-XXII because the transgenic animals are not used in these methods. The methods of inventions VII and VIII, IX and X, XI and XII, XIII and XIV, XV and XVI, XVII and XVIII, XIX and XX, XXI and XXII, and XXV and XXVI are unrelated to each other because they involve different products and method steps, and are directed to different goals and thus have different modes of operation, effects and functions. Invention XVII is unrelated to inventions I-XVI because the transgenic knock-out animals does not comprise any of the claimed products, nor is it used in any of the claimed methods.

Inventions I and II and inventions XI, XII, XVII, and XVIII are related as product and process of use. Inventions III and IV and inventions IX, X, XIII, XIV, XIX, and XX are related as product and process of use. Inventions V and VI and inventions VII, VIII, XI, XII, XV, XVI, XXI, and XXII are related as product and process of use. Inventions XXIII and XXIV and inventions XXV and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of inventions I and II can be used in the methods of inventions XI and XII or of XVII and XVIII, and they can be used to make the antibodies of inventions V and VI. The nucleic acids of inventions III and IV can be used in the methods of inventions IX, X, XIII, XIV, XIX, and XX, and they can be used to make the

antibodies of inventions V and VI. The antibodies of inventions V and VI can be used in the methods of inventions VII, VIII, XI, XII, XV, XVI, XXI, and XXII, and they can be used to affinity purify the polypeptides of inventions I and II. The transgenic animals of inventions XXV and XXVI can be used to study the physiological consequences of overexpressing the polypeptides of inventions I and II in an animal.

Inventions XXIII and XXIV and inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the nucleic acid of the transgenic animal may by any of the variants defined in claim 5. The subcombination has separate utility as a probe in the method of inventions IX and X, or as a therapeutic agent in the methods of inventions XIX and XX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each invention is not required for the other inventions, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
Art Unit 1632